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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,525

01/23/2006

Beate Schmidt

27147U

2907

34375 7590 05/12/2009

NATH & ASSOCIATES PLLC
112 South West Street
Alexandria, VA 22314

EXAMINER

DESAI, RITA J

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

05/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,525	Applicant(s) SCHMIDT, BEATE	
	Examiner Rita J. Desai	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/27/06</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restriction:-

Applicants have elected group I compounds of claims 1-6 and 8 and traversed the restriction that the structure is the special technical feature.

However as explained by the examiner before the core is not novel as given by WO 97/28131 Amschler Hermann et al page 1, line 1 and page 2 line 11, claim 1 and table A. WO 02/05616 Bundschuh et al. (Listed in the IDS). The reference shows compounds with a similar core and hence applicants core is not novel over that of the prior art.

So applicants arguments are not convincing and the lack of Unity still stands.

The examination of claims 1-6 and 8 is as follows.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being obvious over US 10/565526 (US Pub 20060189641), WO 97/28131 Gutterer Beate, WO 00/42018, Flockerzi et al, WO0205616 Bundshun et al, WO 0042020 Flockerzi et al., WO 2005012253 Flockerzi et al.

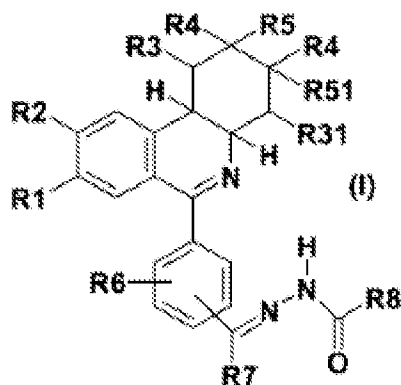
One of the applied reference (20060189641) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by:

(1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference

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was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

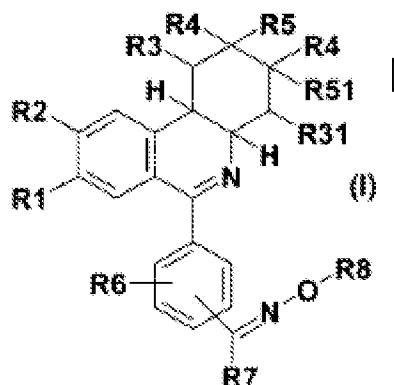
Applicants compounds are drawn to.



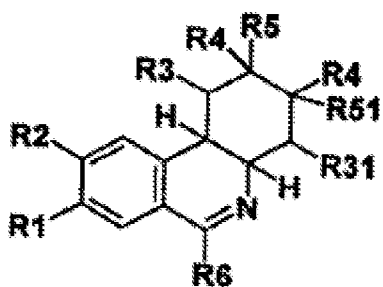
Chemical structure (I)

Scope and content of the Prior art.

The claims are drawn to the same core (US Pub 20060189641 discloses the core



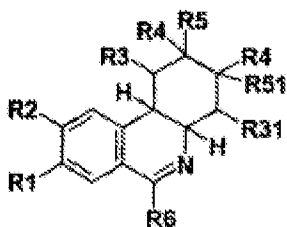
. The prior art WO 97/28131 Gutterer Beate also discloses similar compounds for the same use. (treat respiratory disorders), Compounds of the



formula

wherein R6 is a phenyl.

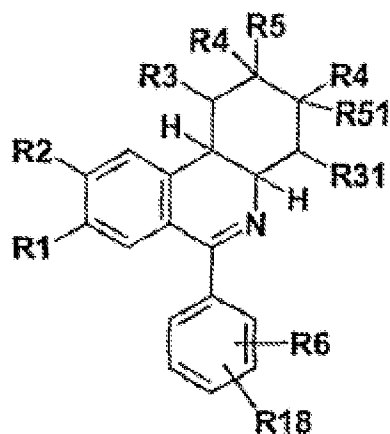
WO 00/42018, Flockerzi et al also discloses compounds of the formula



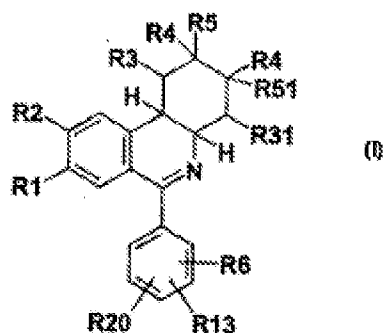
wherein R6 is a phenyl with various options of substituents.

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WO0205616 Bundshun et al also discloses a similar core such as



with R6 and or R18 being various substituent.

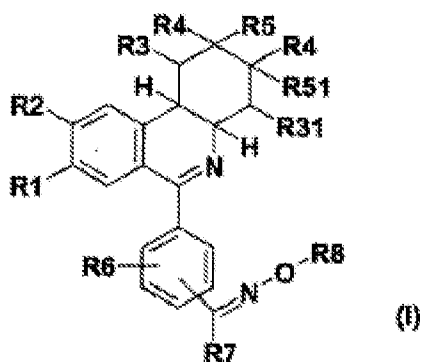


WO 0042020 Flockerzi et al discloses

wherein

R6 can be a amino or aminocarbonyl group.

WO 2005012253 Flockerzi et al. teaches the compounds of the formula



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Difference between Prior Art and the claims MPEP 2141.02

The difference is only on the substituent on the substituent on the phenyl ring.

Again the use of the compounds is the same.

Prima Facie Obviousness , Rational and Motivation MPEP 2142-2413

From the numerous prior art documents it can be seen that the core retains its activity irrespective of the substituent on the phenyl ring. There is no showing of unexpected results that applicants particular substituent has better results. In the absence of unexpected results the compounds are obvious variants of the prior art compounds.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 8 of copending Application No.

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10/565526 (US Pub 20060189641) obvious in view of WO 97/28131 Gutterer Beate, WO 00/42018, Flockerzi et al, WO0205616 Bundshun et al., WO 0042020 Flockerzi et al.

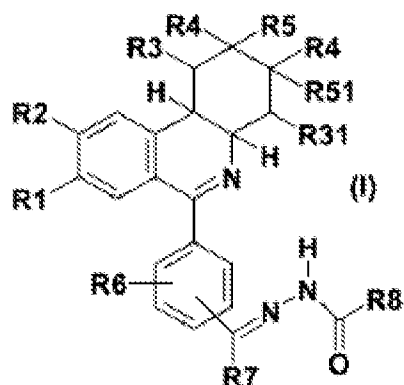
Claims 1-6 and 8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6534518, US 6476025, US 6534519, 6410551, 6191138, 6127,378, 6121,279 in view of each other and WO 97/28131 Gutterer Beate, WO 00/42018, Flockerzi et al, WO0205616 Bundshun et al., WO 0042020 Flockerzi et al.

This is a provisional obviousness-type double patenting rejection over US Pub 20060189641

And an obvious-type double patenting over U.S. Patent No. 6534518, US 6476025, US 6534519 , 6410551, 6191138, 6127,378, 6121,279

Applicants compounds are drawn to.

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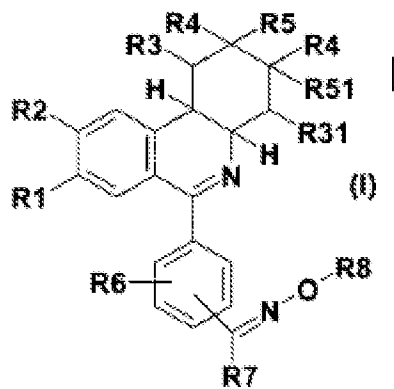


phenyl ring.

with a hydrazine substituent on the

Scope and content of the Prior art.

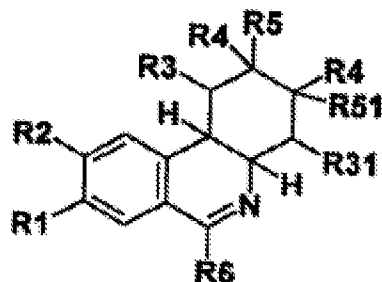
The claims are drawn to the same core (US Pub 20060189641 discloses the core



with an oxime substituent. The prior art WO

97/28131 Gutterer Beate also discloses similar compounds for the same use. (treat respiratory

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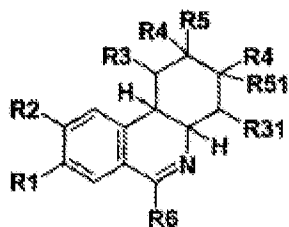


disorders), Compounds of the formula

wherein R6 is a

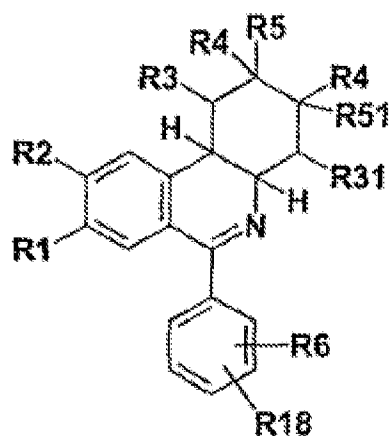
phenyl. And many other substituents on it, including amine, carboxyamine.

WO 00/42018, Flockerzi et al also discloses compounds of the formula



wherein R6 is a phenyl with various options of substituents.

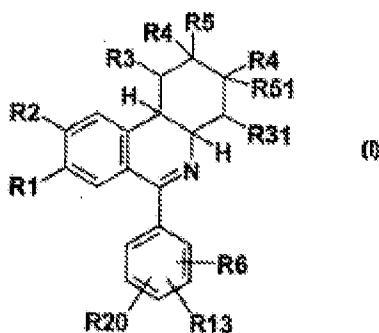
WO0205616 Bundshun et al also discloses a similar core such as



with R6 and or R18 being various substituent.

WO 0042020 Flockerzi et al discloses

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wherein R6 can an amino group or an amino carbonyl group .

Difference between Prior Art and the claims MPEP 2141.02

The difference is only on the substituent on the substituent on the phenyl ring.

Again the use of the compounds is the same.

Prima Facie Obviousness , Rational and Motivation MPEP 2142-2413

From the numerous prior art documents it can be seen that the core retains its activity irrespective of the substituent on the phenyl ring. There is no showing of unexpected results that applicants particular substituent has better results. In the absence of unexpected results the compounds are obvious variants of the prior art compounds.

This is a provisional obviousness-type double patenting rejection.

Conclusion

Claims 1-6 and 8 stand rejected.

Claims 10 and 11 are withdrawn .

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/
Primary Examiner, Art Unit 1625

May 7, 2009